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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,810	07/13/2001	Paul Rennert	A068 US	6397

7590 02/08/2002

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,810	RENNERT, PAUL	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Fax Transmission Restriction Election.

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.

Sequence Compliance

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

3. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

4. The following is noted:

It is noted that Claims 1-22 recite multiple forms of an "agent" employed in the various methods that do not share *a substantial structural feature essential to a common utility.* These structurally distinct agents are subject to restriction, rather than election of species (as per MPEP 803.02), within the context of the particular method.

The restriction has therefore been set forth for each of these "agents" and methods encompassing them as separate groups, irrespective of the format of the claims.

It is noted that page 7, paragraph 8 of the specification discloses that "TWEAK or TWEAK-receptor modifying agent" and "TWEAK or TWEAK-receptor modifying reagent" refers to any agent that can modify ligand binding to a TWEAK receptor. For restriction purposes, it is noted that such agents other than an antibody directed against the TWEAK ligand and an antibody directed against the TWEAK receptor are set forth in the Groups.

If additional structurally distinct "agents" are introduced during the course of prosecution that do not share *a substantial structural feature essential to a common utility* with the instantly recited "agents", then a supplemental restriction requirement may be issued.

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I-V. Claims 1-15, drawn to a method for blocking the development or treating or reducing the severity or effects of an immunological disorder which result from the introduction of foreign antigen comprising administering a pharmaceutical composition comprises a) an antibody directed against the TWEAK ligand; b) an antibody directed against the TWEAK receptor; c) an agent that modifies the binding of the TWEAK ligand to the receptor; d) an agent that modifies the cell surface receptor clustering; and e) an agent that can interrupt the intracellular signaling of the TWEAK receptor, classified in Class 424, subclass 130.1.

VI-X. Claims 1-15, drawn to a method for blocking the development or treating or reducing the severity or effects of autoimmune disorders comprising administering a pharmaceutical composition comprises a) an antibody directed against the TWEAK ligand; b) an antibody directed against the TWEAK receptor; c) an agent that modifies the binding of the TWEAK ligand to the receptor; d) an agent that modifies the cell surface receptor clustering; and e) an agent that can interrupt the intracellular signaling of the TWEAK receptor, classified in Class 424, subclass 130.1.

XI-XV. Claims 1-15, drawn to a method for blocking the development or treating or reducing the severity or effects of acute and chronic inflammatory conditions comprising administering a pharmaceutical composition comprises a) an antibody directed against the TWEAK ligand; b) an antibody directed against the TWEAK receptor; c) an agent that modifies the binding of the TWEAK ligand to the receptor; d) an agent that modifies the cell surface receptor clustering; and e) an agent that can interrupt the intracellular signaling of the TWEAK receptor, classified Class 424, subclass 130.1.

XVI-XX. Claims 16-22, drawn to a pharmaceutical composition comprises a) an antibody directed against the TWEAK ligand; b) an antibody directed against the TWEAK receptor; c) an agent that modifies the binding of the TWEAK ligand to the receptor; d) an agent that modifies the cell surface receptor clustering; and e) an agent that can interrupt the intracellular signaling of the TWEAK receptor, classified Class 435, subclass 7.1.

6. Groups XVI-XX and I-XV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I-XV can be used for affinity purification, in addition to the methods of treating and detecting recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. This application contains claims directed to the following patentably distinct species of the claimed Inventions I-V: wherein the immunological disorder which result from the introduction of foreign antigen is:

A) GVHD, or
B) organ transplant failure resulting from graft rejection.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions VI-X: wherein the autoimmune disorderis:

A) SLE,
B) idiopathic thrombocytopenia purpura,
C) Wegener's granulomatosis,
D) polyarteritis nodosa,
E) retinal Uveitis,
F) rapidly progressive crescentic glomerulonephritis,
G) rheumatoid arthritis,
H) multiple sclerosis, or
I) ulcerative colitis.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. This application contains claims directed to the following patentably distinct species of the claimed Inventions XI-XV: wherein the acute and chronic inflammatory condition is:

A) allergic inflammation,
B) asthma,
C) eosinophilia,
D) Graves' disease, or
E) Chagas' disease.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
January 29, 2002

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
2/7/02